

K082560

## 510(K) Summary

SEP 08 2008

### A. Submitter Information

Submitter's Name: Kettenbach GmbH & Co. KG  
Address: Im Heerfeld 7  
D-35713  
Eschenburg, Germany  
Phone Number: (+49) 2774-705-58  
Fax Number: (+49) 2774-705-33  
Contact Person: Michaela Zinke  
Date of Preparation: July 10, 2008

### B. Device Name

Trade Name: *Panasil® Impression Materials, to include:*

- *Panasil® putty (putty, putty fast set, putty soft)*
- *Panasil® binetics (putty fast, putty soft)*
- *Panasil® tray (fast, soft)*
- *Panasil® monophase*
- *Panasil® contact (two in one, plus)*

Common/Usual Name: Impression Material  
Classification Name: Material, Impression (21 CFR 872.3660, Product Code: ELW)

### C. Predicate Devices

Trade Name: Panasil® Impression Materials (K954281)  
Trade Name: Aquasil Ultra Rigid Smart Wetting® Impression Materials (K021413)  
Trade Name: Aquasil Ultra XLV Smart Wetting® Impression Material (K021410)  
Trade Name: Kerr VPS Impression Material (K050604)

D. Device Description

*Panasil® Impression Materials* are addition-curing, elastomeric materials with hydrophilic properties, high tear strength, dimensional accuracy, and resistance to permanent deformation. The *Panasil Impression Material* family consists of five different viscosities (putty, heavy-bodied, medium-bodied, light-bodied, x-light-bodied), available in an assortment of delivery systems: traditional 1:1 50 ml automix cartridge, 5:1 362 ml foil bags for use in most automatic dispensing and mixing systems, and traditional 1:1 putty jars.

E. Intended Use

The *Panasil® Impression Materials* are intended to:

- be placed on an impression tray (or injected directly into the mouth, depending on the technique and device) and used to reproduce the structure of a patient's teeth and gums;
- provide models for study and for production of restorative prosthetic devices.

Indications for Use

*Panasil putty (putty, putty fast set, putty soft)* and *Panasil binetics (putty fast, putty soft)* are to be used as preliminary materials for:

- Two step putty/wash impression technique.
- One step putty/wash impression technique.
- Two step putty/wash impression technique using a foil (plastic putty spacer)
- One step putty impression technique for forming functional peripheries.

*Panasil tray (fast, soft)* is to be used as a heavy-bodied material for:

- One step impression technique (simultaneous technique) using single or dual viscosities.
- Two step impression technique using dual viscosities.
- Functional impressions.

*Panasil monophase* is to be used as a medium-bodied tray or syringeable impression material for:

- Taking impressions over fixed/removable restorations and implants (transferring impression posts and bridge components).
- Functional impressions.
- Fabricating crown and bridgework or inlays.
- Fabricating full or partial dentures.
- Reline impressions.
- Use in the simultaneous mixing technique as well as the putty/wash and triple tray techniques.
- Transferring root posts when fabricating posts and cores indirectly.

*Panasil contact (two in one, plus)* is to be used as a syringeable impression material for:

- Two step putty/wash impression technique.
- One step putty/wash impression technique.
- One step impression technique using a foil (plastic putty spacer)
- One step impression technique (simultaneous technique) using dual viscosities
- Reline impressions.
- Fabricating full or partial dentures.

#### **F. Technological Characteristics Summary**

The technological characteristics of *Panasil® Impression Materials* are substantially equivalent to the predicate device technological characteristics.

*Panasil Impression Materials (Panasil putty, Panasil binetics, Panasil tray, Panasil monophase, Panasil contact)* and the predicate devices are addition-curing, elastomeric materials designed and manufactured for use as dental impression materials.

G. Performance Data

No performance standards have been established for this type of device.

*Panasil® Impression Materials* have been evaluated in accordance with the applicable criteria established in *Guidance for Industry and FDA Staff: Dental Impression Materials – Premarket Notification (FOD#2203, 8/17/1998)* and *ISO 4823 (Dentistry – Elastomeric impression materials):2000/Cor 1:2004/Amd 1:2007*.

The results of device performance testing demonstrated that *Panasil Impression Materials (Panasil putty, Panasil binetics, Panasil tray, Panasil monophase, Panasil contact)* are suitable for use as dental impression materials. *Panasil Impression Materials (Panasil putty, Panasil binetics, Panasil tray, Panasil monophase, Panasil contact)* have been designed and manufactured to perform in a manner substantially equivalent to that of the predicate devices.



SEP 08 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Kettenbach GmbH & Company KG  
C/O Mr. Stefan Preiss  
Responsible Third Party Official  
TÜV SÜD America, Incorporated  
1775 Old Highway 8 NW, Suite 104  
New Brighton, Minnesota 55112-1891

Re: K082560

Trade/Device Name: Panasil® Putty (Putty, Putty Fast Set, Putty Soft), Panasil®  
Binetics (Putty Fast, Putty Soft), Panasil® Tray (Fast, Soft), Panasil®  
Monophase, Panasil® Contact (Two in One, Plus)

Regulation Number: 872.3660

Regulation Name: Partially Fabricated Denture Kit

Regulatory Class: II

Product Code: ELW

Dated: September 2, 2008

Received: September 4, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu S. Lin".

Chiu S. Lin, Ph. D  
Division Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K082560

Device Name: Panasil® putty (putty, putty fast set, putty soft)

Indications for Use:

**Panasil putty (putty, putty fast set, putty soft) is to be used as a preliminary material for:**

- Two step putty/wash impression technique.
- One step putty/wash impression technique.
- Two step putty/wash impression technique using a foil (plastic putty spacer)
- One step putty impression technique for forming functional peripheries.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K082560

## Indications for Use

510(k) Number (if known): K082560

Device Name: Panasil® binetics (putty fast, putty soft)

Indications for Use:


**Panasil binetics (putty fast, putty soft) is to be used as a preliminary material for:**

- Two step putty/wash impression technique.
- One step putty/wash impression technique.
- Two step putty/wash impression technique using a foil (plastic putty spacer)
- One step putty impression technique for forming functional peripheries.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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## Indications for Use

510(k) Number (if known): K082560

Device Name: Panasil® tray (fast, soft)

Indications for Use:

**Panasil tray (fast, soft) is to be used as a heavy-bodied material for:**

- One step impression technique (simultaneous technique) using single or dual viscosities.
- Two step impression technique using dual viscosities.
- Functional impressions.

Prescription Use X  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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## Indications for Use

510(k) Number (if known): 1082560

Device Name: Panasil® monophasic

Indications for Use:

**Panasil monophasic is to be used as a medium-bodied tray or syringeable impression material for:**

- Taking impressions over fixed/removable restorations and implants (transferring impression posts and bridge components).
- Functional impressions.
- Fabricating crown and bridgework or inlays.
- Fabricating full or partial dentures.
- Reline impressions.
- Use in the simultaneous mixing technique as well as the putty/wash and triple tray techniques.
- Transferring root posts when fabricating posts and cores indirectly.


Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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10(k) Number: 1082560

## Indications for Use

510(k) Number (if known): K082560

Device Name: Panasil® contact (two in one, plus)

Indications for Use:

**Panasil contact (two in one, plus) is to be used as a syringeable impression material for:**

- Two step putty/wash impression technique.
- One step putty/wash impression technique.
- One step impression technique using a foil (plastic putty spacer)
- One step impression technique (simultaneous technique) using dual viscosities
- Reline impressions.
- Fabricating full or partial dentures.

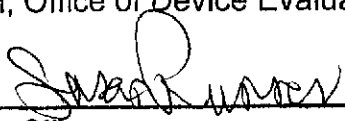
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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